



POINT OF CARE  
SKIN STEROL TEST

Version 2.01

Spectrophotometer System  
Getting Started Guide

English



*Consumer Healthcare  
Soins-santé grand public*



## **Spectrophotometer**

Model Name: Spectrophotometer  
X-Rite Model No.: MD22

McNeil Product Code: 331350

## **Federal Communications Commission Notice**

**NOTE:** This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

## **Industry Canada Compliance Statement**

This Class A digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe A est conforme à la norme NMB-003 du Canada.

## **Equipment Classifications**



Attention



Type BF Equipment



Class II Equipment IEC Publication 417-5172

**Ingress** – Ordinary Equipment

**Sterilization/Disinfection** – Does not apply

**Application Safety** – Not suitable for use in the presence of flammable anaesthetic

**Mode of Operation** – Short-Time Operation (1 sec.)

## CE Declaration

Directive(s) Conformance: EMC 89/336/EEC  
MDD 93/42/EEC

Manufacturer: X-Rite, Incorporated  
Manufacturer's Address: 3100 44<sup>th</sup> Street, S.W.  
Grandville, Michigan 49418  
U.S.A.

Supplied to: IMI International Medical Innovations, Inc.  
4211 Yonge St., Suite 615  
Toronto, Ontario, M2P 2A9  
Canada

Distributor: McNeil Consumer Healthcare, Canada  
890 Woodlawn Rd. West  
Guelph, Ontario, N1K 1A5  
Canada



Use only X-Rite 100-240VAC power supply P/N SE30-85 (manufacturer's P/N WM10-12V), or X-Rite 120VAC power supply P/N SE30-84 (manufacturer's P/N UPFN12-01M) to operate the instrument.



No user serviceable parts in this product.

## Kits

Manufacturer: IMI International Medical Innovations, Inc.  
4211 Yonge St., Suite 615  
Toronto, Ontario, M2P 2A9  
Canada

Authorized Representative  
in EU: MDCI, Ltd.  
International Business Centre  
Spindle Way, Crawley, West Sussex  
RH10 TG, UK

Distributor: **McNeil Consumer Healthcare, Canada**  
890 Woodlawn Rd. West  
Guelph, Ontario, N1K 1A5  
Canada

For inquiries or  
product orders: Toll-Free U.S. and Canada  
1 866 283-8328  
[www.prevu.com](http://www.prevu.com)  
Tel: (519) 836-3856  
Fax: (519) 826-6205

## **Limited Warranty**

The product manufacturer (X-Rite, Incorporated) warrants each unit manufactured to be free of defects in material and workmanship for a period of twelve months. If the fault has been caused by misuse or abnormal conditions of operation, repairs will be billed at a nominal cost. In this case, an estimate will be submitted before work is started upon request. The unit shall be returned with transportation charges prepaid.

**There are no warranties of merchantability or fitness. This warranty obligation is limited to servicing the unit returned to X-Rite, Incorporated for that purpose.**

X-Rite, Incorporated offers a repair program for instruments out of warranty. For more information, please contact McNeil Customer Healthcare Customer Service Department (1 866 283-8328) to discuss any warranty issues or to get more information on the instrument repair program. Always include the product serial number in any correspondence concerning the unit. The serial number is located on the bottom of the instrument.

This agreement shall be interpreted in accordance with the laws of the State of Michigan and jurisdiction and venue shall lie with the courts of Michigan as selected by X-Rite, Incorporated.

## **Table of Contents**

<b>INTRODUCTION .....</b>	<b>1-1</b>
How To Use This Manual.....	1-1
Getting Help .....	1-1
Packaging Content.....	1-2
<b>SYSTEM SETUP .....</b>	<b>2-1</b>
System Requirements .....	2-1
Connecting the Instrument To Your Computer .....	2-1
Installing the PREVU* POC Software .....	2-4
<b>GETTING STARTED.....</b>	<b>3-1</b>
Starting The Software .....	3-1
The Opening Screen .....	3-1
Selecting the Instrument COM Port.....	3-3
Performing Tests.....	3-3
Instrument Calibration .....	3-4
<b>INSTRUMENT MAINTENANCE .....</b>	<b>4-1</b>
Repair Information.....	4-1
Cleaning the Instrument.....	4-1
Cleaning the Calibration Standard.....	4-2
Replacing the Measurement Shoe.....	4-2
<b>APPENDIX .....</b>	<b>5-1</b>
Technical Support.....	5-1
Instrument Specifications .....	5-2

## SECTION ONE

# Introduction

---

PREVU\* Point of Care (POC) Skin Sterol Test is a two step chemical-enzyme skin test carried out on the palm of the hand. In the first step, a chemical solution (Detector) consisting of two concentrations of a digitonin-horseradish peroxidase conjugate is placed on the palmar surface of hand for one minute. This solution binds to skin sterol (predominantly skin tissue cholesterol) in the skin's sterol rich surface layer. After one minute the palm is blotted dry with paper towel. A second solution (Indicator) is added to the test sites for two minutes. This solution changes from colourless to a blue colour in the presence of the Detector enzyme. Negative and positive controls are used to monitor test performance. Results are determined using the PREVU\* POC spectrophotometer system.

## HOW TO USE THIS MANUAL

This manual is intended to provide installation procedures, an overview of PREVU\* POC, and general instrument maintenance. Specific application information is available in the PREVU\* POC online help file.

## GETTING HELP

The system Help provides a broad look at PREVU\* POC allowing you to move step-by-step through a detailed description of the program.

To open the Help system, click the **Question Mark (?)** button or press **F1** on the keyboard. You can select topics from a table of contents, look for topics using an index of keywords, or perform a full-text search of all topics. In addition, many topics include links to other related topics. Links, identified by underlined text, appear in the text of a topic. These links allow you to quickly move to related topics in the Help system.

## PACKAGING CONTENT

Your PREVU\* POC system packaging should contain all the items listed below. If any of these items are missing, contact your dealer.

- Spectrophotometer Instrument with Dual-Plug Interface Cable.
- Power Supply— either X-Rite 100-240VAC power supply P/N SE30-85 (manufacturer's P/N WM10-12V), or X-Rite 120VAC power supply P/N SE30-84 (manufacturer's P/N UPFN12-01M).
- Calibration Reference with White Ceramic and Serial Number Plate on bottom.
- CD containing PREVU\* POC application.
- Documentation Material.

# System Setup

## SYSTEM REQUIREMENTS

To install and use the PREVU\* POC software with the instrument, you need the following system requirements:

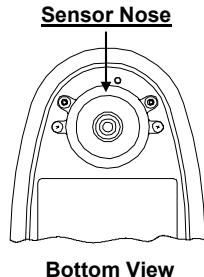
- A PC-compatible Pentium computer with an available RS-232 serial port.
- Windows® 98SE, 2000, or XP
- 128 MB RAM recommended
- CD-ROM drive.

## CONNECTING THE INSTRUMENT TO YOUR COMPUTER



DO NOT contact the instrument's sensor nose with any sharp tools or abrasive objects. Doing so can damage the anodized coating protecting the sensor nose.

If the anodized coating becomes damaged, please contact the McNeil Customer Service Department to arrange for replacement of the sensor nose. Replacement assures safe operation and patient protection.



Bottom View

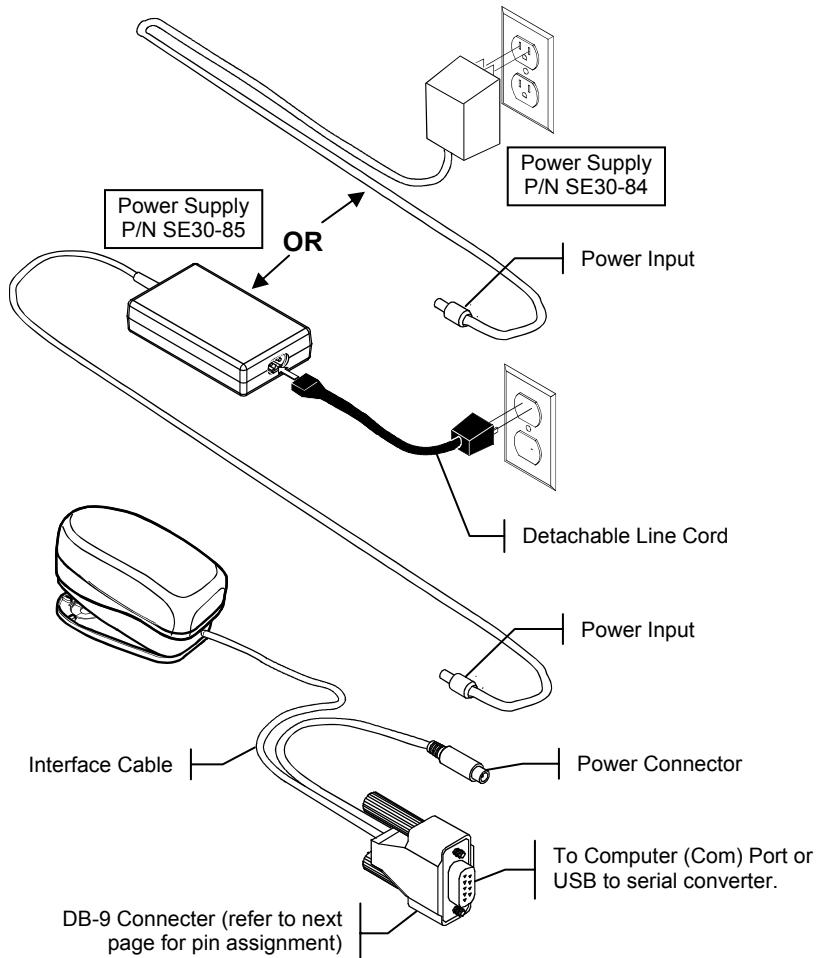
1. Close all software programs and shut down your computer.
2. Remove the instrument from its packaging and unwrap the cable ends.
3. Attach the DB-9 connector to an available RS-232 (Com) port on back of the computer. Secure it with the thumbscrews.

**NOTE:** As an alternative to connecting the DB-9 connector to your computer, a USB to serial converter can be used to connect the instrument to a USB port on your computer. Refer to the instructions supplied with your converter for installation details. Depending on which COM ports are available on your computer, you must map your "USB to serial converter" into one of the unused COM1, COM2, COM3, or COM4 ports.



Use only X-Rite 100-240VAC power supply P/N SE30-85 (manufacturer's P/N WM10-12V), or X-Rite 120VAC power supply P/N SE30-84 (manufacturer's P/N UPFN12-01M) to operate the instrument.

4. Plug the power input from the power supply into the power connector on the interface cable.
5. **For power supply SE30-84**, plug the power supply into the AC wall receptacle. **For power supply SE30-85**, plug the appropriate line cord for your region into the power supply and then plug the line cord into the AC wall receptacle.
6. Turn on your computer.
7. Refer to Section Three, Selecting the Instrument Com Port.





**NOTE:** If the instrument is ever disconnected from the Com port, turn off your computer before re-connecting.

#### DB9 RS-232 Pin Assignment

Pin 1	Not Used
Pin 2	TXD (transmit data)
Pin 3	RXD (receive data)
Pin 4	Not Used
Pin 5	Digital Ground
Pin 6	Not Used
Pin 7	Not Used
Pin 8	Not Used
Pin 9	Not Used

## **INSTALLING THE PREVU\* POC SOFTWARE**

1. Insert the PREVU\* POC CD into your drive. The install program starts automatically.  
If it doesn't start automatically, double-click the **setup.exe** file located on the CD.
2. Select Language from the drop down list and click OK.
3. Follow the remainder of the installation instructions on your computer screen.

## SECTION THREE

# Getting Started

## STARTING THE SOFTWARE

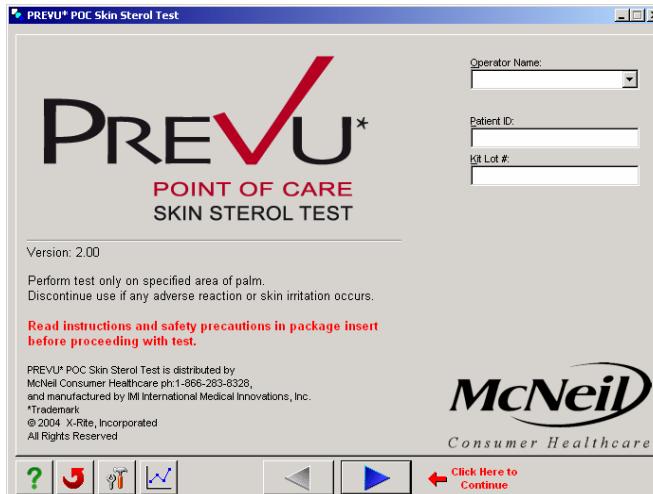
 (PREVU\* POC Program Icon) Once you have installed PREVU\* POC, you can start the program by double-clicking the program icon in the appropriate program group folder. You can also open the Windows **Start** menu, and then choose the application from the appropriate program folder on the **Programs** menu.



**NOTE:** The software Com port is set to Com 1 by default. If your instrument is not attached to this port, you will need to change the Com port setting. Refer to **Selecting the Instrument Com (RS-232) Port** later in this section.

## THE OPENING SCREEN

The PREVU\* POC opening screen consists of six buttons and three entry fields.



### Operator Name

The operator name should refer to the person performing the test. (i.e. your name) Once an operator name has been entered into the editable list, it will be added to the dropdown list of operators.

**Patient ID**

The Patient ID is a unique identifier that is assigned for each patient. Each test will be tagged with the entered Patient ID.

**Kit Lot #**

The Lot # can be found on a label attached to your kit.

**Help button**

The **Help** button displays the help file. If you press **F1** from any step, the help file will automatically jump to the topic for the step being performed.

**Restart button**

The **Restart** button allows you to completely delete the current test and restart the entire testing process. This should only be used if some unforeseen problem prevents you from completing the current test. This will only delete the current test.

**Options button**

The **Options** button is used to access the RS-232 Com port selection, Instrument Calibration, and Database Backup procedure. This button only appears on the first screen of this application.

**Patient History button**

The **Patient History** button allows you to view the skin sterol readings over time for any patient. This button only appears on the first screen of this application.

**Back button**

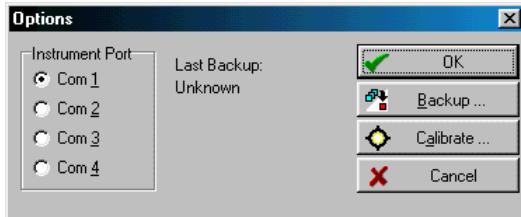
The **Back** button allows you to move backward a step. This is useful if you accidentally selected "Next" or need to review previous instructions. For normal operation you should not need to use the **Back** button because this test must be executed in a smooth progression from the first to the last step.

**Next button**

Use the **Next** button to progress through each step of the PREVU\* POC procedure. Upon completion of tasks for the current step, click **Next** to immediately go to the next step. When the test is complete, this button will automatically restart the test process for a new patient.

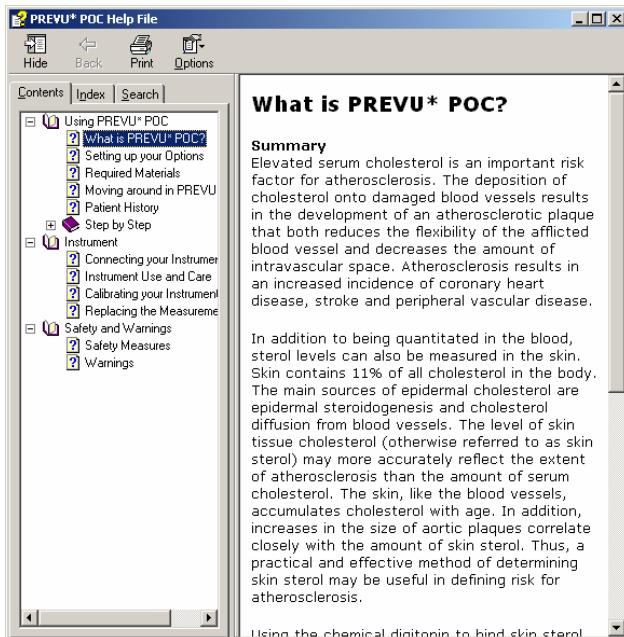
## SELECTING THE INSTRUMENT COM PORT

1. Click the Options button at the bottom of the opening screen.
2. Click the appropriate **Com** radio button from the Instrument Port group.
3. Click the OK button to select option and close dialog.



## PERFORMING TESTS

Please review the online help system before performing a test. The help system contains step-by-step information on patient preparation, measurement techniques and procedures.



## INSTRUMENT CALIBRATION

Periodically, you will need to calibrate your spectrophotometer. The program automatically prompts you when the instrument is in need of a calibration (every time the program is started or once a day). If desired, you can manually activate the calibration procedure through the Options button. When you start the software, it will force you to calibrate your instrument.

Calibration is a simple procedure where you measure the instrument's white calibration standard.



**NOTE:** Make sure the calibration standard is clean before use. See Section Four for cleaning procedure.

1. When prompted by the program for a calibration (or if manually activated), place the calibration reference on top of the instrument shoe so that it is properly aligned. Refer to the online help system for graphic illustrations on proper positioning.
2. Lower the instrument to the calibration standard and hold approximately three seconds.
3. Once completed, a "calibration successful" message appears in the calibration dialog. Release the instrument and remove the calibration standard.
4. Click the Close button on the Instrument Calibration dialog.



**NOTE:** If a calibration error message containing "factory service may be required" is repeatedly displayed, you should contact McNeil Customer Service at: 1 866 283-8328.

## SECTION FOUR

# Instrument Maintenance

## REPAIR INFORMATION

The spectrophotometer instrument is covered by a one-year limited warranty and should be referred to a factory or authorized service center for necessary repairs within the warranty period. Attempts to make repairs within this time frame may void the warranty.

Factory repair service is available to McNeil customers. Because of the complexity of the circuitry, all repairs should be referred to the factory or an authorized service center. Please contact McNeil Customer Service (1 866 283-8328) for more information.

## CLEANING THE INSTRUMENT

It is important that your instrument is kept very clean. The exterior of the instrument may be wiped clean with a cloth dampened in water whenever required.

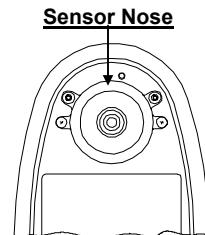
You should take care to remove ALL liquid from its shoe after each test.



**NOTE:** Do not use any solvents to clean the instrument, this causes damage to the cover.



DO NOT contact the instrument's sensor nose with any sharp tools or abrasive objects. Doing so can damage the anodized coating protecting the sensor nose. If the anodized coating becomes damaged, please contact McNeil Customer Service to arrange for replacement of the sensor nose. Replacement assures safe operation and patient protection.



**Bottom View**

## CLEANING THE CALIBRATION STANDARD

If your white reference target needs to be cleaned, follow these instructions:

The reference target should be cleaned using a mild soap and warm water solution, thoroughly rinsed with warm water, and wiped dry with a lint-free cloth. You MUST let the calibration standard dry completely before taking a calibration reading.

Do not use solvents or cleaners of any kind.

## REPLACING THE MEASUREMENT SHOE

The measurement shoe is the clear test holder attached to the bottom of your instrument's shoe. It is designed to facilitate easy cleaning or replacement if it becomes damaged.



**NOTE:** Never turn the instrument upside down when liquid is present on the shoe.

1. Remove the existing measurement shoe by rotating it to the unlocked position. Refer to the online help system for graphical illustrations.
2. Align the new measurement shoe perpendicular to the instrument shoe opening.
3. Rotate the new measurement shoe into the locked position.

## SECTION FIVE

# Appendix

---

## TECHNICAL SUPPORT

The McNeil Consumer Healthcare Customer Service Department is fully staffed to assist you with your technical questions. McNeil will arrange contact with X-Rite, Incorporated and their qualified technicians should repair or replacement of your spectrophotometer be necessary. When you contact McNeil, please include the following information:

- Your software version and instrument serial number
- Your name and your company name
- Your telephone number
- A written copy of the error message related to your problem (if applicable)
- A written copy of the steps you were performing before the problem occurred

When contacting technical support via telephone, you will also want to have the software running within easy reach.

### **by telephone:**

1 866 283-8328 or (519) 836-3856

Customer Service Centre hours of operation are 8:30 AM – 4:30 PM Eastern Standard Time.

### **via the internet:**

For online customer service contact, please visit:

[www.prevu.com](http://www.prevu.com)

## INSTRUMENT SPECIFICATIONS

### **Spectral Sensor**

- DRS spectral engine
- 16 band, 400 – 700nm spectral range
- 20 nanometer interval, 45°/0° geometry
- meeting ISO and ANSI standards
- 3.2mm diameter measuring area

### **Performance**

- 0 to 200% measurement range, no warm-up time
- .2 DE max short-term repeatability on white
- <1 DE max, <.5 DE average inter-instrument agreement (as compared to X-Rite 900 series)
- 2 seconds per measurement

### **Power Requirements**

- 12v DC (lamp for 2 seconds, 200ma idle) AC power supply, 100-240VAC X-Rite P/N SE30-85 (manufacturer's P/N WM10-12V), or 120VAC X-Rite P/N SE30-84 (manufacturer's P/N UPFN12-01M) included

### **Environmental**

- +10° to +40°C operating
- 30% to 76% RH non-condensing

### **Physical**

- Dimensions: 2.7”H (6.9cm), 3.0”W (7.6cm), 5.4”L (13.7cm)
- Net-Weight: 12 ounces (340 g)

### **Safety Classification**

- UL 2601-1
- CSA C22.2 No. 601-1
- IEC 601-1

### **EMC FCC**

- Part 15, Class A, Digital Device

### **Canada**

- ICES-03 Issue 2, Revision 1

### **International**

- Generic Emission EN50081-1:1992
- Generic Immunity Requirement EN50082-1:1995

Copyright © 2004 by X-Rite, Incorporated.

**\*Trademark**

X-Rite is a registered trademark of X-Rite, Incorporated. Windows is a registered trademark of Microsoft Corporation. All other logos, product names, and trademarks mentioned are the property of their respective holders.



Soins-santé grand public McNeil  
890, chemin Woodlawn Ouest  
Guelph (Ontario) N1K 1A5  
Canada

Tél. : (519) 836-3856  
Téléc. : (519) 826-6205  
Numéro sans frais aux États-Unis et au Canada :  
1 866 283-8328  
[www.prevu.com](http://www.prevu.com)

McNeil Consumer Healthcare  
890 Woodlawn Rd. West  
Guelph, Ontario, N1K 1A5  
Canada

Tel: (519) 836-3856  
Fax: (519) 826-6205  
Toll-Free U.S. and Canada:  
1 866 283-8328  
[www.prevu.com](http://www.prevu.com)